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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,393	12/11/2001	Kevin P. Baker	GNE.2830P1C46	9822

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EXAMINER

HAMUD, FOZIA M

ART UNIT PAPER NUMBER

1647

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/015,393	Applicant(s) BAKER ET AL.	
	Examiner Fozia M Hamud	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09/20/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's preliminary amendment canceling claims 1-27 and adding new claims 28-47, filed on 11 December 2001 is acknowledged.

Thus claims 28-47 are pending and under consideration.

2. **Priority:**

2a. Based on the information given by Applicants and an inspection of the patent applications, the Examiner has concluded that the subject matter defined in this application is supported by the disclosure in application serial no. 09/946,374 filed on 04 September 2001, because, EXAMPLE 150 (Assay #110) on page 512 of Application no. 09/946,374, provides a specific and substantial asserted utility or a well established utility for the nucleic acid of SEQ ID NO:116 (PRO1430). Example 150 discloses that the polypeptide of SEQ ID NO:116 encoded by the claimed nucleic acid induces re-differentiation of chondrocytes, therefore, said polypeptide is expected to be useful for the treatment of various bone and/or cartilage disorders such as, for example, sports injuries and arthritis. However, none of the other prior applications disclose this assay, thus they fail to satisfy the requirements under 35 U.S.C. 112. Accordingly, the subject matter defined in claims 28-47, is afforded an effective filing date of 04 September 2001, which is the filing date of the U.S application No. 09/946,374.

Should the applicant disagree with the examiner's factual determination above, it is incumbent upon the applicant to provide the serial number and specific page number(s) of any parent application filed prior to 09/04/01, which specifically supports the particular claim limitation for each and every claim limitation in all the pending claims

which applicant considers to have been in possession of and fully enabled for prior to 09/04/01.

Claim Rejections under 35 U.S.C. §112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3a. Claims 28-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid comprising the nucleotide sequence set forth in SEQ ID NO:116, an isolated nucleic acid comprising a nucleotide sequence which completely hybridizes to the nucleotide sequence set forth in SEQ ID NO:115, said nucleic acid encoding the polypeptide of SEQ ID NO:116, does not reasonably provide enablement for an isolated nucleic acid having at least 80%, 85%, 95% or 99% sequence identity to the nucleic of SEQ ID NO:115, or to nucleic acid which encodes the polypeptide of SEQ ID NO:116. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Instant claims 28-33 are drawn to nucleic acid having at least 80%, 85%, 90%, 95% or 99% to the nucleic acid of SEQ ID NO:115, or having at least 80%, 85%, 90%, 95% or 99% to nucleic acid encoding the polypeptide of SEQ ID NO:116, however, instant specification does not teach how to make or use said nucleic acid. Instant specification discloses that the polypeptide of SEQ ID NO:116 encoded by the claimed nucleic acid induces re-differentiation of chondrocytes, therefore, said polypeptide is

expected to be useful for the treatment of various bone and/or cartilage disorders such as, for example, sports injuries and arthritis, (see Example 150, assay 110 on page 512). Therefore, only the full length polypeptide of SEQ ID NO:116 encoded nucleic acid of SEQ ID NO:115 can be used for said treatments, because Applicants have not shown that variants of the polypeptide of SEQ ID NO:116, induce chondrocyte re-differentiation.

Instant claims 28-33 are drawn to a genus of nucleic acids that are defined only by sequence identity. Due to the large quantity of experimentation necessary to determine all the nucleic acids comprising a nucleotide sequence that is at least 80%, 85%, 90%, 95% or 99% identical to the nucleic acid of SEQ ID NO:115, and to screen for the ones that encode the polypeptide of SEQ ID NO:116, the lack of direction/guidance presented in the specification regarding which variants of the nucleic acid of SEQ ID NO:115 would retain the desired activity, the complex nature of the invention, the absence of working examples directed to variants of the nucleic acid of SEQ ID NO:115, the state of the prior art establishing that biological activity cannot be predicted based on structural similarity, the unpredictability of the effects of mutation on the structure and function of the claimed polypeptide, and the breadth of the claims which fail to recite particular biological activities, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

3b. Claims 28-47 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The instant claims 28-32 are drawn to an isolated nucleic acid that shares "80%, 85%, 90%, 95% or 99%" identity to the nucleic acid of SEQ ID NO:115, and claims 41-47 are drawn to an isolated nucleic acid which hybridize to a nucleic acid encoding a specific polypeptide. However, the instant specification only describes the structure of the nucleic acid of SEQ ID NO:115, and therefore, conception is not achieved until reduction to practice has occurred. With respect to claims drawn to nucleic acid encoding the "extracellular domain" of the polypeptide of SDEQ ID NO:116, instant specification does not disclose the structure of said extracellular domain. Adequate written description requires more than a mere statement that it is part of the invention. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity. There is not even identification of any particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. *Vas-cath Inc. v. Mahurkar*, 19 USPQ2d 1111, clearly states "applicant must convey with

reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." (See Vas-cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. Therefore, only the isolated nucleic acid set forth in SEQ ID NO: 115, but not the full breadth of the claims meet the written description provision of 35 U.S.C. §112, first paragraph.

Claim Rejections - 35 U.S.C. § 112, second paragraph:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 41-47 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4a. Claims 41 and 42 recite "... Hybridizes under stringent conditions...", however, this is a conditional term and renders the claims indefinite. This rejection could be

obviated by supplying specific conditions supported by the specification, which Applicants consider to be "stringent".

Claims 43-47 are also rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, so long as they depend from claim 41 for the limitations set forth directly above.

Claim Rejections - 35 U.S.C. §102(b):

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5a. Claims 28-33 are rejected under U.S.C. § 102 (b) as being anticipated by Baker et al (WO200012708; published 09 March 2000).

Baker et al disclose an isolated polypeptide that shares 100% homology to the polypeptide of SEQ ID NO:116 of the instant application. (See attached copies of the comparison of SEQ ID NO:116 of the instant invention and the sequence of the reference (SEQUENCE COMPARISON 'A'). Baker et al also disclose a vector comprising said nucleic acid and a host cell comprising said vector, (see pages 104-105 figures 65 and 66; and claims).

Instant claims 28-47 are drawn an isolated nucleic acid comprising the nucleic acid of SEQ ID NO:115, encoding the polypeptide of SEQ ID NO:116, a vector comprising said nucleic acid and a host cell comprising said vector. Therefore, the Baker et al reference meets all the limitations recited in instant claims 28-47.

Accordingly, the Baker et al reference anticipates the instant claims 28-47 in the absence of any evidence to the contrary.

5b. Claims 41-43 are rejected under U.S.C. § 102 (b) as being anticipated by Waterston, R.H. (Accession Number AC019238; published 17 August 2000).

Waterston, discloses an isolated nucleic acid that shares 53.3% over all homology to the claimed nucleic acid of SEQ ID NO:115 and shares 99.7% to nucleotides 841-1808 of instant SEQ ID NO:115. See attached copies of the comparison of SEQ ID NOs:115, claimed in the instant invention and the sequences of the references (SEQUENCE COMPARISON 'B'). The nucleic acid disclosed by Waterston, meets the "at least 10 nucleotides" limitation recited in instant claim 43. Furthermore, the complement of the nucleic acid disclosed by Waterston would be expected to hybridize to the nucleic acid of SEQ ID NO:115, thus meeting the limitation recited in instant claims 41 and 42.

Therefore the Waterston reference anticipates the instant claims 41-43 in the absence of any evidence to the contrary.

Conclusion:

6. No claim allowed.


Advisory Information:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (571) 272-0884. The examiner can normally be reached on Monday, Thursday-Friday, 6:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Fozia Hamud
Patent Examiner
Art Unit 1647
25 June 2004


JANET ANDRES
PATENT EXAMINER